

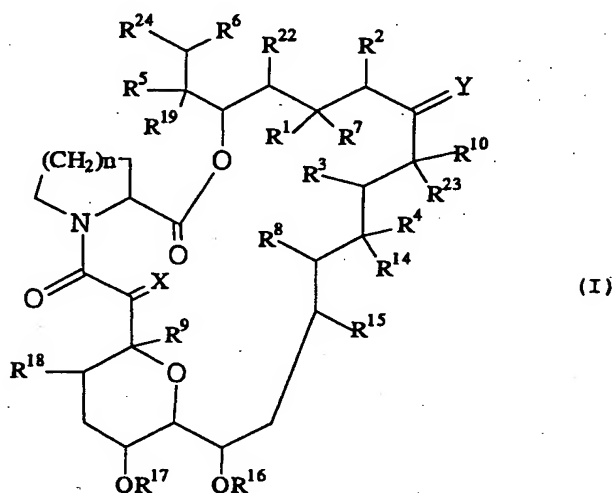
**WHAT IS CLAIMED IS**

1. A method of treating a human patient suffering from dry eye, wherein prior to treatment said patient has a Schirmer score of less than or equal to seven millimeters per five minutes, said method comprising administering to the patient an ophthalmic composition containing a macrolide compound.
2. A method according to claim 1, wherein prior to treatment said patient has a Schirmer score of less than or equal to five millimeters per five minutes.
3. A method according to claim 2, wherein said ophthalmic composition contains from about 0.01% to about 0.1% of said macrolide compound.
4. A method according to claim 3, wherein said ophthalmic composition contains from about 0.03% to about 0.06% of said macrolide compound.
5. A method according to claim 4, wherein said ophthalmic composition contains about 0.03% of said macrolide compound.
6. A method according to claim 1, wherein said macrolide compound is FK506.
7. A method according to claim 1, wherein said ophthalmic composition is an eye drop.
8. A method according to claim 7, wherein said eye drop further contains polyvinyl alcohol.

9. A method according to claim 7, wherein said eye drop contains about 0.03% of said macrolide compound.

10. A method according to claim 7, wherein said eye drop is administered from about one to about four times per day.

11. A method according to claim 1, wherein said macrolide compound has the following formula (I) or a pharmaceutically acceptable salt thereof:



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wherein adjacent pairs of R<sup>1</sup> and R<sup>2</sup>, R<sup>3</sup> and R<sup>4</sup>, and R<sup>5</sup> and R<sup>6</sup> each independently

a) consist of two adjacent hydrogen atoms, wherein R<sup>2</sup> is optionally alkyl, or

15 b) form another bond optionally between carbon atoms binding with the members of said pairs;

R<sup>7</sup> is hydrogen atom, hydroxy, alkyloxy or protected hydroxy, or may form oxo with R<sup>1</sup>;

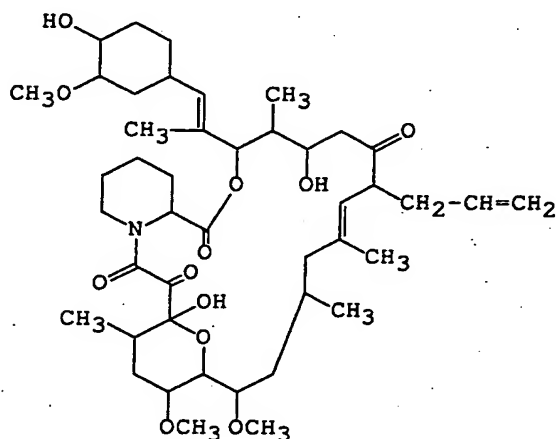
R<sup>8</sup> and R<sup>9</sup> each independently show hydrogen atom or hydroxy;

20 R<sup>10</sup> is hydrogen atom, alkyl, alkyl substituted by one or more hydroxy, alkenyl, alkenyl substituted by one or more hydroxy or alkyl substituted by oxo;

Y is oxo, (hydrogen atom, hydroxy), (hydrogen atom, hydrogen atom), or a group of the formula  $\text{N-NR}^{11}\text{R}^{12}$  or  $\text{N-OR}^{13}$ :

R<sup>13</sup>, R<sup>14</sup>, R<sup>15</sup>, R<sup>16</sup>, R<sup>17</sup>, R<sup>18</sup>, R<sup>19</sup>, R<sup>22</sup> and R<sup>23</sup> each independently show hydrogen atom or alkyl;

12. A method according to claim 11, wherein said macrolide compound has the following structure:



13. A method according to claim 1 or 2, wherein prior to treatment said patient also has a superficial punctate keratitis (SPK) score of at least two.

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15. A method of treating a human patient suffering from dry eye, wherein prior to treatment said patient has a superficial punctate keratitis (SPK) score of at least two, said method comprising administering to the patient an ophthalmic composition containing a macrolide compound.
16. A method of treating a human patient suffering from an ocular surface damage associated with dry eye, wherein prior to treatment the patient has a superficial punctate keratitis (SPK) score of at least two, said method comprising administering to the patient an ophthalmic composition containing a macrolide compound.
17. A method of treating a human patient suffering from an ocular discomfort associated with dry eye, wherein prior to treatment the patient has a Schirmer score of less than or equal to seven millimeters per five minutes, said method comprising administering to the patient an ophthalmic composition containing a macrolide compound.
18. A method of treating a human patient suffering from an ocular discomfort associated with dry eye, wherein prior to treatment the patient has a superficial punctate keratitis (SPK) score of at least two, said method comprising administering to the patient an ophthalmic composition containing a macrolide compound.
19. A method of treating a human patient suffering from an ocular surface damage associated with dry eye, wherein prior to treatment the patient has a Schirmer score of less than or equal to seven millimeters per five minutes, said method comprising administering to the patient an ophthalmic composition containing a macrolide compound.